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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,759	11/21/2005	Sol Green	68-05	2582

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EXAMINER	
HILL, KEVIN KAI	
ART UNIT	**PAPER NUMBER**
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,759	GREEN ET AL.	
	Examiner	Art Unit	
	Kevin K. Hill, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1-12, 19-23 and 28, drawn to an isolated polynucleotide encoding a multifunctional germacrene-D synthase, wherein the synthase comprises an amino acid sequence with at least 60% similarity to SEQ ID NO:2, a genetic construct comprising said polynucleotide.

Group II, Claims 29 and 32, drawn to a host cell which has been genetically modified with an isolated polynucleotide encoding a multifunctional germacrene-D synthase and a method of preparing a compound, wherein the method comprises culturing said host cell.

Group III, Claims 30-31, 33-36, drawn to a transgenic plant cell comprising an isolated polynucleotide encoding a multifunctional germacrene-D synthase, wherein the synthase comprises an amino acid sequence with at least 60% similarity to SEQ ID NO:2, a transgenic plant comprising said transgenic plant cell, a method of making a transgenic plant, and a method for modulating germacrene-D production in a plant.

Group IV, Claims 13-18 and 41-44, drawn to an isolated multi-functional germacrene-D synthase polypeptide and a method for preparing a sesquiterpene comprising incubating farnesyl dipohsphate in the presence of said polypeptide.

Group V, Claims 24-27, drawn to a genetic construct encoding a polynucleotide that is antisense to a polynucleotide encoding the polypeptide of SEQ ID NO:2.

Group VI, Claims 37-40, drawn to a polynucleotide fragment of SEQ ID NO:1 and a method of selecting a selecting a plant.

2. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.47(d) also states:

"If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c). "

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. The prior art discloses a polynucleotide encoding germacrene-D synthase (Guterman et al, 2001), and thus the polynucleotide does not contribute over the prior art.

In the instant application, the technical feature of Group I is a polynucleotide encoding a germacrene-D synthase polypeptide which is not present in Groups IV-VI. The special technical feature of Group II is a host cell, wherein Applicant contemplates the host cell to include non-plant host cells (see below), which is not present in Groups I and III-VI. The special technical feature of Group III is a transgenic plant, which is not present in Groups I-II and IV-VI. The special technical feature of Group IV is an isolated polypeptide which is not present in Groups I-

III and V-VI. The special technical feature of Group V is an antisense molecule which is not present in Groups I-IV and VI. The special technical feature of Group VI is a polynucleotide fragment which is not present in Groups I-V. The method of using the Group IV isolated polypeptide has different objectives, requires different method steps, and yields different effects than the Group VI method of using a polynucleotide fragment to select plants, and the Group III method of making a transgenic plant. Each of the compositions of Groups I-VI has distinctly different functions, is mutually exclusive of the others and yields distinctly different effects. It is also noted that Applicant contemplates diverse non-plant recombinant expression systems and transgenic hosts, including bacteria, yeast, insect and mammals (pg 18, line 10; pg 23, lines 15-16). And thus, the Group III transgenic plant is separable from the Group II host cell.

A search for a transgenic plant would not be co-extensive with a search for recombinant mammalian cell expression systems. Further, a reference rendering a polynucleotide probe as anticipated or obvious over the prior art would not necessarily also render an isolated polypeptide as anticipated or obvious over the prior art. Similarly, a finding that an isolated polypeptide was novel and unobvious over the prior art would not necessarily extend to a finding that a method for screening transgenic plants was also novel and unobvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper.

3. **Should Applicant elect any of Groups I-IV or VI a species restriction is required under 35 U.S.C. 121 and 372.** This application contains claims, Claims 3, 32-33, 35-36, 38 and 41, directed to more than one species of compounds created as a result of a polypeptide enzymatic activity. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In response to the restriction requirement, Applicant must further elect a single species, specifically:

i) germacrene-D,

ii) delta-cadinene,

iii) delta-elemene,

iv) elemol,

v) gamma-muurolene,

vi) gamma-cadinene,

vii) gamma-elemene,

viii) germacrene-B, or

ix) a specific combination of (i)-(viii).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The claims are drawn to a polypeptide, or variant thereof, having the ability to catalyze the synthesis of one or more structurally distinct compounds. Furthermore, the enzymatic activity is recited to yield each compound in the alternative or as a combination, and thus each product is both mutually exclusive and non-obvious variation of the others. Given the breadth of the claimed, unrelated structures, a search for all possible species imposes a substantial burden on the Office. As the technical feature, a polypeptide, linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

A search for germacrene-D would not be co-extensive with a search for delta-elemene. Further, a reference rendering germacrene-B as anticipated or obvious over the prior art would not necessarily also render elemol as anticipated or obvious over the prior art. Similarly, a finding that an enzyme capable of synthesizing only one compound was novel and unobvious over the prior art would not necessarily extend to a finding that an enzyme capable of synthesizing all compounds was also novel and unobvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper.

Applicant is required to elect a single named compound species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should Applicant add or amend the claims of the elected invention to introduce subject matter from a non-elected invention for which the above stated group restriction(s) and/or species election(s) is(are) required, then Applicant is required to make the appropriate elections set forth above in accordance with the subject matter recited in the newly added or amended claims.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kevin K. Ho

Q. JANICE LI, M.D.
PRIMARY EXAMINER